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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,883

09/19/2003

Chong-Sheng Yuan

466992001100

6779

25225 7590 05/12/2008

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
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SAN DIEGO, CA 92130-2040

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

05/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,883	<b>Applicant(s)</b> YUAN, CHONG-SHENG	
	<b>Examiner</b> Richard G. Hutson	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 12, 21-34, 37-42, 44-48, 50-55, 58-65 and 67-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☒ Claim(s) 1, 12, 21-23, 31-34, 37-42, 44-48, 50-55, 58-65 and 67-72 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's cancellation of claims 2-11, 13-20, 35, 36, 43, 49, 56, 57 and 66, the amendment of claims 1, 21, 31, 39, 45, 50, 60 and 68, in the paper of 2/19/2008, is acknowledged. Claims 1, 12, 21-34, 37-42, 44-48, 50-55, 58-65, 67-72 are still at issue and are present for examination.

Applicants' arguments filed on 2/19/2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 24-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Information Disclosure Statement***

Applicants filing of an information disclosure statement on 11/9/2007, is also acknowledged.

### ***Specification***

The disclosure is objected to because of the following informalities:

Applicants previously submitted sequence listing submitted, in the paper of 1/11/2007, is objected to because the sequence of SEQ ID NO: 4 is different than that which previously existed and is thus considered new matter. It is realized that a previous objection to applicant's specification was made in the paper of 10/18/2007.

Applicants presented arguments which explained the previous situation and applicants pointed to applicant's specification at page 13, paragraph [0050] for support of applicant's position. Applicants complete explanation is acknowledged, however is not found persuasive on the basis that at the very least the sequence to which applicants refer to on page 13 paragraph [0050] has a poly-histidine tail of six histamines at the C-terminus. Applicants submitted SEQ ID NO:4 has seven, not six histamines as a part of the poly-A tail. Thus it continues that the sequence submitted for SEQ ID NO: 4 on 1/11/2007, is considered new matter.

Appropriate correction and/or explanation is required.

### ***Claim Objections***

Claim 1, 12, 21-23, 31-34, 37-42, 44-48, 50-55, 58-65, 67-72 are objected to because of the following informalities:

Claim 1 (12, 21-23, 31-34, 37-42, 44-48, 50-55, 58-65, 67-72 dependent on) recites "a first peptide fragment comprising a first bacterial leader sequence comprising..." As there is no "second" bacterial leader sequence, applicants recitation of the word "first" twice with in the context of the above recitation is cumbersome and confusing and it is suggested that the second "first" be eliminated to maintain consistency with the rest of the claim and not complicate the claimed subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is drawn to a chimeric protein which comprises the amino acid sequence set forth in SEQ ID NO: 4, and also lists a sequence in parenthesis, however, this sequence is not the same as SEQ ID NO: 4 listed in applicants newly submitted sequence listing. Specifically the sequence of SEQ ID NO: 4 has six terminal histidine residues, while the sequence listed in claim 23 has seven terminal histidine residues. For this reason applicants reference to SEQ ID NO: 4 and to the sequence in the parenthesis together is confusing and unclear and thus indefinite.

Appropriate correction or explanation is requested.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgH  
5/1/2008

/Richard G Hutson, Ph.D./  
Primary Examiner, Art Unit 1652